

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/981,248	Confirmation No.	6008
Appellant	:	Mark A. Hoffman, et al		
Filed	:	10/16/2001		
Group Art Unit	:	1631		
Examiner	:	Marjorie A. Moran		
Title	:	COMPUTER SYSTEM FOR PROVIDING INFORMATION ABOUT THE RISK OF AN ATYPICAL CLINICAL EVENT BASED UPON GENETIC INFORMATION		
Atty. Docket No.	:	CRNL83071		
Customer No.	:	46169		

EFS – 07/31/2006

APPELLANT'S APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an Appeal from a Final Office Action dated 02/28/2006, rejecting claims 25-30, 55-60, and 85-91. These claims have been at least twice rejected. Appellant, having filed a Notice of Appeal (filed 05/30/2006) within the time period provided under § 1.134 accompanied by the fee set forth in 37 C.F.R. § 41.20(b)(1), do hereby submit this Brief prior to the two-month deadline of 07/30/2006 along with the fee set forth in § 41.20(b)(2). The Commissioner is hereby authorized to charge any additional fee that may be due, or credit any overpayment, to Deposit Account No. 19-2112.

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I. REAL PARTY IN INTEREST

The real party in interest is Cerner Innovation, Inc., a corporation of the State of Delaware, United States of America.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 25-30, 55-60, and 85-91 are pending, and the rejection of each of those claims is being appealed.

IV. STATUS OF AMENDMENTS

No amendments have been filed subsequent to the Final Office Action dated 2/28/2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The instant Application includes four independent claims, claims 25, 55, 85, and 91.

Claim 25

Claim 25 recites a method in a computer system for processing hereditary data related to the use of clinical agents by a person. The method comprises receiving a genetic test result value for the person and querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. It is determined if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, a list of risk-associated agent is accessed and an interpretation of the genetic test result value and the list of risk-associated agents are output.

Claim 55

Claim 55 recites a computer system for processing hereditary data related to the use of clinical agents by a person. The system comprises a receiving component that receives a genetic test result value for the person and a querying component for querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. The system further comprises a first determining component that determines if the genetic test result value is a polymorphism value associated with an atypical clinical event, an accessing component that accesses a list of risk-associated agents if the determining component determines that a genetic test result value is a polymorphism value associated with an atypical event, and an outputting component that outputs an interpretation of the genetic test result value and the list of risk-associated agents.

Claim 85

Claim 85 recites a computer-readable medium containing instructions for processing hereditary data related to the use of clinical agents by a person. The instructions comprise receiving a genetic test result value for the person and querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. The instructions further comprise determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents and outputting an interpretation of the genetic test result value and the list of risk-associated agents.

Claim 91

Claim 91 recites a method in a computer system for processing hereditary data related to the use of clinical agents by a person. The method comprises receiving a genetic test result value for the person and querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values. The method further comprises determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents. An interpretation of the genetic test result value and the list of risk-associated agents are output and it is determined if the person has been exposed to an agent on the list of risk-associated agents.

VI. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

A) Claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-91 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference (Internal Medicine (July 2000) Vol. 39, no. 7, pp. 523-524) in view of the Evans reference (Science (Oct. 1999) Vol. 286, pp. 487-491) and the Reinhoff reference (U.S. Patent Application Publication No. 2002/0049772, filed 5/26/2000).

B) Claims 28, 58 and 88 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference in view of the Evans reference and the Reinhoff reference and in further view of Fey et al. (U.S. Patent Application Publication No. 2002/0038227, filed 2/26/2001).

Appellant respectfully traverses all these rejections.

VII. ARGUMENT

A) The rejection of claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-91 under 35 U.S.C. § 103(a) as being obvious over the Ichikawa reference and in view of the Evans reference and the Reinhoff reference should be reversed because the Examiner has failed to establish a *prima facie* case of obviousness.

The basic requirements of a *prima facie* case of obviousness are summarized in MPEP § 2143 through § 2143.03. In order “[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success [in combining the references]. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).” MPEP § 2143. Further, in establishing a *prima facie* case of obviousness, the initial burden is placed on the Examiner. “To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).” *Id.* See also MPEP § 706.02(j) and § 2142.

Obviousness Rejection Based on the Ichikawa, Evans and Reinhoff References

Claims 25-27, 29-30, 55-57, 59-60, 85-87 and 89-91 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference (Internal Medicine (July 2000) Vol. 39, no. 7, pp. 523-524) in view of the Evans reference (Science (Oct. 1999) Vol.

286, pp. 487-491) and the Reinhoff reference (U.S. Patent Application Publication No. 2002/0049772, filed 5/26/2000). Appellants submit that there is no suggestion or motivation to modify or combine the references, without hindsight there would be no reasonable expectation of success by an ordinary person skilled in the art just before this invention was made. Appellants further submit that Ichikawa, in view of Evans and Reinhoff, fails to teach or suggest all the limitations of the rejected claims and traverse this rejection.

1. There is no Motivation to combine the teachings on Ichikawa with Evans and Reinhoff

In making the rejection under § 103(a) the Examiner combined the Ichikawa reference with the Evans reference and the Reinhoff reference. There is no suggestion or motivation to modify these references or to combine them. Further, the MPEP states that “[t]o reach a proper determination under 35 U.S.C. § 103, the examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made.” MPEP § 2142. The Examiner has not located or pointed to any suggestion in the art to combine the three references in the manner suggested by the Examiner. Instead, the Examiner has simply summarily concluded that it would be obvious to one of ordinary skill in the art to combine the three references to get Appellant’s claimed invention. Such is not a proper rejection under § 103 and is the ultimate based upon hindsight reasoning. The Court of Appeals for the Federal Circuit has repeatedly held that in order for a rejection of a claim under § 103 to be proper, there must be a suggestion to combine or modify the prior art in the manner suggested. See Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 43 USPQ2d 1294 (Fed. Cir. 1997) (“It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements.”) In re Geiger, 815 F.2d 686,

688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987) (Obviousness cannot be established by combining pieces of prior art absent some “teaching, suggestion, or incentive supporting the combination.”)

The Examiner states that “it would have been obvious to one of ordinary skill in the art at the time of invention to have computerized, or automated, the genetic screening method of Ichikawa, as taught by Reinhoff, and to have accessed a list of treatment/drug options, as taught by Evans, in the automated method of Ichikawa and Reinhoff, where the motivation would have been to use the method to identify patients appropriate for treatment when a choice is to be made among various options, as taught by Reinhoff.”

Even if Reinhoff can be combined with Ichikawa and Evans, although Appellants do not concede that it can, the mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 1990) and MPEP § 2134.01, emphasis added. Appellants submit that no suggestion nor motivation to modify Ichikawa and Evans or to combine Ichikawa and Evans with Reinhoff exists. Rather, the Reinhoff reference teaches a computer program product for separating individuals into subpopulations using a polymorphic profile in a networked environment. Reinhoff says that when a polymorphism is known to be associated with a response to known treatment, this information may be used to allocate the most appropriate dose to subjects enrolled in a treatment study such as a clinical trial. (Reinhoff, Paragraph 0057). The polymorphic profiles of individuals can determine the degree of response of individuals to the known treatment. Appellants submit that one of skill in the art would not use the Reinhoff reference as a motivation to computerize or automate accessing a list of risk-associated agents and outputting

the list of risk-associated agents because the treatment is already known. As the treatment to be used in clinical trials as discussed in the Reinhoff reference is already known, there is no need to access a list of risk-associated agents and output the list of risk-associated agents.

Appellants respectfully note that it is impermissible to use the claimed invention as an instruction manual or template to piece together the teaching of the prior art so that the claimed invention is rendered obvious. The Office Action cannot use hindsight to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fritch*, 972 F.2d 1260, 23 USPQ 2d 1780 (Fed. Cir. 1992). Appellants respectfully submit hindsight is employed to assert that claims 25, 55, 85 and 91 are rendered obvious by Ichikawa in view of Evans and Reinhoff.

2. Reasonable Expectation of Success

There must be a reasonable expectation of success. The Office Action offers no reasons as to why one skilled in the art should reasonably expect to succeed in making Appellants' claimed invention from combining Reinhoff with Ichikawa and Evans as there is no need to access and output a list of risk-associated agents in Reinhoff as the treatment (agent) is already known.

As a *prima facie* case of obviousness has not been made for independent claims 25, 55, 85 and 91, Appellants request withdrawal of the § 103(a) rejection of these claims. Further, as claims 26-27, 29-30, 56-57, 59-60, 86-87 and 89-90 depend directly or indirectly from independent claims 25, 55, 85 and 91, Appellants request withdrawal of the rejection of these claims as well.

3. The references, alone or in combination, fail to teach or suggest all the claim features

Appellants submit that the Ichikawa reference fails to teach or suggest the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claims 25 and 91. The Ichikawa reference fails to teach or suggest, a computer system for processing hereditary data related to the use of clinical agents by a person that includes an accessing component for accessing a list of risk-associated agents if the determining component determines that a genetic test result value is a polymorphism value associated with an atypical event and an outputting component for outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 55. Also, the Ichikawa reference fails to teach or suggest instructions on a computer readable medium that includes accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 85.

Rather, the method of the Ichikawa reference teaches that a particular single nucleotide polymorphism can be used to disclose severe side effects or proper dosage for a patient. The Ichikawa reference lacks any teaching or suggestion of the computerized steps of accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents in a computer system. The Ichikawa reference merely teaches a patient with an autosomal recessive trait for TMPT deficiency may show severe and potentially fatal leukopekia if treated with aqathioprine or mercaptopurine. There is no suggestion in the Ichikawa reference to automate accessing a list

of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting interpretation of one or more genetic test result values and a list of risk-associated agents in a computerized system without user intervention.

Like Ichikawa, the Evans reference also fails to teach or suggest a method in a computer system including the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claims 25 and 91. The Evans reference also fails to teach or suggest, a method in a computer system for processing hereditary data related to the use of clinical agents by a person that includes automated computer components such as an accessing component for accessing a list of risk-associated agents for a genetic test result value and an outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 55. Also, the Evans reference fails to teach or suggest instructions on a computer readable medium that includes accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 85.

Rather, the Evans reference discloses translating functional genomics into rational therapeutics. The Evans reference provides examples of clinically relevant genetic polymorphisms influencing drug metabolism and effects. The Evans reference lacks any teaching or suggestion of computerized steps for accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents. The Evans reference merely chronicles the fact that automated systems are being developed to determine an individual's genotype for polymorphic genes. The discussion

of automated systems is limited to automated systems for determining an individual's genotype and does not discuss accessing and outputting a list of risk-associated agents for a particular genotype. There is no teaching or suggestion in Evans that an automated computer system may be used to associate an individual's genotype for a polymorphic gene with a list of risk-associated agents and outputting a list of risk-associated agents.

Appellants submit that the Reinhoff reference fails to teach or suggest, the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claims 25 and 91. The Reinhoff reference fails to teach or suggest, a computer system for processing hereditary data related to the use of clinical agents by a person that includes an accessing component for accessing a list of risk-associated agents if the determining component determines that a genetic test result value is a polymorphism value associated with an atypical event and an outputting component for outputting component for outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 55. Also, the Reinhoff reference fails to teach or suggest instructions on a computer readable medium that includes accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents, as recited in independent claim 85.

Rather, Reinhoff discloses that when a polymorphism is known to be associated with a response to a known treatment, this information may be used to allocate the most appropriate dose to subjects enrolled in a treatment study such as a clinical trial. (Reinhoff, Paragraph 0057) The polymorphic profiles of individuals can determine the degree of response

of individuals to the known treatment. A list of risk-associated agents is not accessed and as the treatment is already known. As such, there is no teaching or suggestion in Reinhoff that an automated computer system may be used to associate an individual's genotype for a polymorphic gene with a list of risk-associated agents and outputting a list of risk-associated agents.

Appellants submit that Ichikawa in view of Evans and Reinhoff fails to teach or suggest all the limitations of the independent claims 25, 55, 85 and 91 and traverse this rejection. Further, as claims 26-27, 29-30, 56-57, 59-60, 86-87 and 89-90 depend directly or indirectly from independent claims 25, 55, 85 and 91, Appellants request withdrawal of the rejection of these claims as well.

B) The rejection of claim 28, 58, and 88 under 35 U.S.C. § 103(a) as being obvious over the Ichikawa and in view of Evans, Reinhoff, and Fey should be reversed because the Examiner has failed to establish a *prima facie* case of obviousness.

Obviousness Rejection Based on the Ichikawa, Evans, Reinhoff and Fey
References

Claims 28, 58 and 88 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ichikawa reference in view of the Evans reference and the Reinhoff reference and in further view of Fey et al. (U.S. Patent Application Publication No. 2002/0038227, filed 2/26/2001). Appellants submit that the Ichikawa reference in view of the Evans reference and Reinhoff reference and in further view of the Fey reference fail to teach or suggest all of the limitations of claims 28, 58 and 88.

1. The references, alone or in combination, fail to teach or suggest all the claim features

As discussed above, the Ichikawa, Evans, and Reinhoff references fail to teach or suggest all of the limitations of independent claims 25, 55, 85 and 91. Dependent claims 28,

58 and 88 depend either directly or indirectly from independent claims 25, 55, 85 and 91. The Fey reference also fails to teach or suggest all of the limitations of independent claims 25, 55, 85 and 91.

The Fey reference also fails to teach or suggest a method in a computer system for processing hereditary data related to the use of clinical agents by a person that includes the computerized steps of accessing a list of risk-associated agents if a genetic test result value is a polymorphism value associated with an atypical event and outputting an interpretation of one or more genetic test result values and a list of risk-associated agents as recited in independent claims 25 and 91, an accessing component and outputting component as recited by independent claim 55 and instructions for accessing a list of risk-associated agents and outputting the list of risk-associated agents as recited by independent claim 85.

Rather, the Fey reference discloses a method for centralized health data management. The Fey reference relates to a centralized health screening and management system. Data and test results are transmitted to a centralized data management system for analysis and storage in a manner that is accessible for report generation and aggregate information analysis. The Fey reference in no way suggests instructions for accessing a list of risk-associated agents and outputting an interpretation of one or more genetic test results values and a list of risk-associated agents as recited by independent claim 85. The Fey reference merely discusses storing health data in a manner that is accessible. The Fey reference does not suggest computerized steps for accessing a list of risk-associated agents for a genetic test result value that is a polymorphism value associated with an atypical event nor does it suggest outputting a list of risk-associated agents.

Appellants submit that the Ichikawa reference in view of the Evans reference and Reinhoff reference and in further view of the Fey reference fail to teach or suggest all of the limitations of claims 25, 55, 85 and 91 from which claims 28, 58 and 88 depend either directly or indirectly. As such, Appellants request withdrawal of the § 103(a) rejection of claims 28, 58 and 88.

2. There is no Motivation to combine the teachings on Ichikawa with Evans, Reinhoff and Fey

The Office Action states that “it would have been obvious to one of skill in the art at the time of invention to accessed the medical records in the method of Ichikawa, Evans and Reinhoff in a comprehensive healthcare system/database, as taught by Fey, where the motivation would have been to associate phenotypic information specific for a patient with genotypic information in a clinical setting in order to better treat/test the patient, as taught by Reinhoff (paragraph 67).”

Again, Reinhoff cannot be combined with Ichikawa, Evans and Fey as it does not suggest the desirability of the combination. *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 1990) and MPEP § 2134.01. Appellants submit that no suggestion nor motivation exists to modify Ichikawa and Evans or to combine Ichikawa and Evans with Reinhoff exists. Rather, the Reinhoff reference teaches that it is appropriate to exclude individuals in a clinical trial of a known therapy if it is known they will present a particular phenotype. Again, the therapy used for the clinical trial is known. Appellants submit that one of skill in the art would not use the Reinhoff reference as a motivation to computerize or automate accessing a list of risk-associated agents and outputting the list of risk-associated agents because therapy is already known. As the therapy to be used in clinical

trials as discussed in the Reinhoff reference is already known, there is no need to access a list of risk-associated agents and outputting the list of risk-associated agents.

As a *prima facie* case of obviousness has not been made for independent claims 25, 55, 85 and 91, from which claims 28, 58 and 88 depend either directly or indirectly, Appellants request withdrawal of the § 103(a) rejection of claims 28, 58 and 88.

In light of the above arguments, Appellants submit that claims 25-30, 55-60, and 85-91 are in condition for allowance. As such, Appellants respectfully request that a timely Notice of Allowance be issued in this case. Should there be any unresolved matters, please contact the undersigned.

Respectfully submitted,



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Appendices follow.

VIII. CLAIMS APPENDIX

25. A method in a computer system for processing hereditary data related to the use of clinical agents by a person, comprising the steps of:

receiving a genetic test result value for the person;

querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values;

determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents; and

outputting an interpretation of the genetic test result value and the list of risk-associated agents.

26. The method of claim 25, further comprising the step of determining if the person has been exposed to an agent on the list of risk-associated agents.

27. The method of claim 26, wherein the step of determining if the person has been exposed includes accessing an electronic medical record of the person.

28. The method of claim 27, wherein the electronic medical record is stored within a comprehensive healthcare system.

29. The method of claim 26, further comprising the step of initiating a clinical action if the person has been exposed to an agent on the list of risk-associated agents.

30. The method of claim 29, wherein the clinical action is generating an electronic message to inform a clinician to no longer administer the agent.

55. A computer system for processing hereditary data related to the use of clinical agents by a person, comprising:

- a receiving component that receives a genetic test result value for the person;

- a querying component for querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values;

- a first determining component that determines if the genetic test result value is a polymorphism value associated with an atypical clinical event;

- an accessing component that accesses a list of risk-associated agents if the determining component determines that a genetic test result value is polymorphism value associated with an atypical event; and

- an outputting component that outputs an interpretation of the genetic test result value and the list of risk-associated agents.

56. The computer system of claim 55, further comprising a second determining that determines if the person has been exposed to an agent on the list of risk-associated agents.

57. The computer system of claim 56, wherein the second determining component determines if the person has been exposed includes an accessing component that accesses an electronic medical record of the person.

58. The computer system of claim 57, wherein the electronic medical record is stored within a comprehensive healthcare system.

59. The computer system of claim 56, further comprising an initiating component that initiates a clinical action if the person has been exposed to an agent on the list of risk-associated agents.

60. The computer system of claim 59, wherein the clinical action is generating an electronic message to inform a clinician to no longer administer the agent.

85. A computer-readable medium containing instructions for processing hereditary data related to the use of clinical agents by a person, comprising the steps of:

receiving a genetic test result value for the person;

querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values;

determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents; and

outputting an interpretation of the genetic test result value and the list of risk-associated agents.

86. The computer-readable medium of claim 85, further comprising the step of determining if the person has been exposed to an agent on the list of risk-associated agents.

87. The computer-readable medium of claim 86, wherein the step of determining if the person has been exposed includes accessing an electronic medical record of the person.

88. The computer-readable medium of claim 87, wherein the electronic medical record is stored within a comprehensive healthcare system.

89. The computer-readable medium of claim 86, further comprising the step of initiating a clinical action if the person has been exposed to an agent on the list of risk-associated agents.

90. The computer-readable medium of claim 89, wherein the clinical action is generating an electronic message to inform a clinician to no longer administer the agent.

91. A method in a computer system for processing hereditary data related to the use of clinical agents by a person, comprising the steps of:

receiving a genetic test result value for the person;

querying a computerized table listing polymorphism values and atypical clinical events associated with the polymorphism values;

determining if the genetic test result value is a polymorphism value associated with an atypical clinical event, and if so, accessing a list of risk-associated agents;

outputting an interpretation of the genetic test result value and the list of risk-associated agents; and

determining if the person has been exposed to an agent on the list of risk-associated agents.

IX. EVIDENCE APPENDIX

Not applicable

X. RELATED-PROCEEDINGS APPENDIX

Not applicable